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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,108	10/05/2005	Hans-Kervin Bruins	GIL-16108	3576
7609	7590	10/08/2008	EXAMINER	
RANKIN, HILL & CLARK LLP 925 EUCLID AVENUE, SUITE 700 CLEVELAND, OH 44115-1405				SOROUSH, ALI
ART UNIT		PAPER NUMBER		
1616				
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10/08/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/535,108	BRUINS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ALI SOROUSH	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 24 June 2008.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 28-52 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 28-52 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 06292008.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Acknowledgement of Receipt***

Applicant's response filed on 02/14/2008 and 06/24/2008 to the Office Action mailed on 11/15/2007 and the notice of a non-responsive reply mailed on 05/28/2008 is acknowledged.

### ***Status of the Claims***

Claims 1-27 are cancelled, claims 28-42 were newly added on 02/14/2008 and claims 43-52 were newly added on 06/24/2008. Therefore claims 28-52 are currently pending examination for patentability.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 28-32, 34-36, and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blum et al. (US Patent 5885600, Published 03/23/1999) in view of Watanabe et al. (Rotundial a New Natural Mosquito Repellent from the Leaves of Vitex rotundifolia, Published 1995) further in view Hernandez et al. (Biological activities of crude plant extracts from trifoliate L. (Verbenaceae), Published 1999).

### ***Applicant Claims***

Applicant claims a method of repelling arthropods comprising applying to a product, area, and or surface a repellent composition comprising at least one portion of the plant Vitex agnus-castus.

### ***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

Blum et al. teach, "Insect repellents have been used for centuries to prevent insects from annoying humans and animals alike. Repellents have also been used to prevent insect harm to such items as food, clothing, and furniture." (See column 1, Lines 15-19). "A composition that has insect repellent properties is made from cold processed extracted oils and an antioxidant ..." (See abstract). The composition may further

comprises a solvent, UV absorber or stabilizer, and antioxidants (such as butylated hydroxytolune and ascorbyl palmitate). (See columns 7-8, claims 1-17). The extracted oil is taught by Blum et al. to be a suitable alternative to other repellents such as DEET that are can be harmful to children and/or the environment. (See column 1, Lines 21-67). "The resultant composition may then be formulated into many different items, such as lotions, sprays, and creams for use on humans, animals and vegetation." (See column 2, Lines 49-51). "The various compositions work effectively against arachnids (spiders, ticks, mites), caterpillars, cockroaches, silver fish, moths, slugs, bees, yellow jackets, beetles, aphid, meals bugs, green flies, horse flies, gnats, mosquitoes, and chiggers." (See column 6, Lines 19-23).

Watanabe et al. teach, "A new mosquito repellent was isolated from fresh leaves of Vitex rotundifolia. Its structure was elucidated by an extensive NMR spectral analysis to be a cyclopentene dialdehyde named rotundial. This compound possessed potent repelling activity against Aedes aegypti." (See abstract). "Vitex rotundifolia has long been used as a medicinal plant, and various compounds ... have been identified in this plant. It has also been reported that the leaves and twigs of this plant can be used for repelling mosquitoes. However, the principle responsible for its activity has not been previously studied. Since N,N-diethyl-m-toluamide (Deet), the active ingredient in almost all the commercial insect-repellent formulations, has many defects such as an unpleasant odor and skin irritation, a new repellent without such drawbacks is sought." (See page 1979, column 1, paragraph 1).

Hernandez et al. teach, "The genus Vitex (Verbenaceae) approximately includes 270 known species of trees and shrubs within tropical and sub-tropical regions, although a few species may be found in temperate zones." (See page 37, column 1, Lines 1-4). "Several Vitex species are used as folk remedies ..." (See page 37, column 2, Lines 1-2). *V. agnus-castus* is known to have activity as an antimicrobial and in treating diarrhea and gastrointestinal affections. (See page 37, column 2, Lines 6-14). "It is well known that a considerable number of plant species, besides their popular use as medicines in many countries, possess insecticidal activities. The genus Vitex sp. is not an exception." (See page 38, column 1, Lines 5-8). Hernandez et al. further teach that both *V. negundo* and *V. rotundifolia* have shown insect repellent activity and other Vitex species are being investigated for pest control activity. (See page 38, column 1, Lines 9-19).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims***

***(MPEP §2141.012)***

Blum et al. lacks a teaching wherein the repellent composition comprises a portion or extract of the plant *Vitex agnus-castus*. This deficiency is cured by the teachings of Watanabe et al. and Hernandez et al.

***Finding of Prima Facie Obviousness Rational and Motivation***  
***(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add an insect repellent extract isolated from the leaves of *Vitex agnus-castus*, as suggested by Watanabe et al. and Hernandez et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Watanabe et al. teach that an insect repellent extract from *Vitex rotundifolia* is suitable and more advantageous alternative to DEET as are the oil extracts taught by Blum et al. Hernandez et al. teach that a variety of *Vitex* species possess compounds with insect repellent properties. Therefore, it would have been obvious to one of ordinary skill in the art to use extracts of *Vitex agnus-castus* as an insect repellent to be added to the composition taught by Blum et al.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

2. Claims 28, 29, 31-34, and 36-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross (International Application Published Under the PCT WO 98/23150, Published 06/04/1998) in view of Watanabe et al. (Rotundial a New Natural Mosquito Repellent from the Leaves of *Vitex rotundifolia*, Published 1995) further in view Hernandez et al. (Biological activities of crude plant extracts from *trifolia L.* (Verbenacea), Published 1999).

***Applicant Claims***

Applicant claims a method of repelling arthropods comprising applying to a product, area, and or surface a repellent composition comprising at least one portion of the plant Vitex agnus-castus. Applicant further claims a composition comprising at least one portion of the plant Vitex agnus-castus and a secondary insect repellent.

***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

Ross teaches, “The invention relates to storage stable insect repellent emulsion formulations containing N,N-Diethyl-m-toluamide, together with water, a film former polymer and an emulsifier-emulsion stabilizer.” (See abstract). “Other components, while not required, are commonly included in skin care products to enhance the feel of the material upon application to treat dry skin conditions and/or to protect the formulation against microbial contamination. These include emollients, fragrances, preservatives, vitamins, humectants, skin conditioners, antioxidants and others. Any such materials may be included as desired, in addition to the required components. Sunscreening ingredients are also useful optional components of the formulations ...” (See page 4, Lines 27-37). “[A]ctive sunscreen ingredients, such as ... titanium dioxide ... are approved for use in many countries and may be also be incorporated into the insect repellent formulations of the present invention.” (See page 5, Lines 15-20). Ross teaches that such repellent compositions are useful against insects such as mosquitoes, flies, ticks, wasps, and bees. (See page 1, Lines 13-20).

Watanabe et al. teach, "A new mosquito repellent was isolated from fresh leaves of *Vitex rotundifolia*. Its structure was elucidated by an extensive NMR spectral analysis to be a cyclopentene dialdehyde named rotundial. This compound possessed potent repelling activity against *Aedes aegypti*." (See abstract). "*Vitex rotundifolia* has long been used as a medicinal plant, and various compounds ... have been identified in this plant. It has also been reported that the leaves and twigs of this plant can be used for repelling mosquitoes. However, the principle responsible for its activity has not been previously studied. Since N,N-diethyl-m-toluamide (Deet), the active ingredient in almost all the commercial insect-repellent formulations, has many defects such as an unpleasant odor and skin irritation, a new repellent without such drawbacks is sought." (See page 1979, column 1, paragraph 1).

Hernandez et al. teach, "The genus *Vitex* (Verbenaceae) approximately includes 270 known species of trees and shrubs within tropical and sub-tropical regions, although a few species may be found in temperate zones." (See page 37, column 1, Lines 1-4). "Several *Vitex* species are used as folk remedies ..." (See page 37, column 2, Lines 1-2). *V. agnus-castus* is known to have activity as an antimicrobial and in treating diarrhea and gastrointestinal affections. (See page 37, column 2, Lines 6-14). "It is well known that a considerable number of plant species, besides their popular use as medicines in many countries, possess insecticidal activities. The genus *Vitex* sp. is not an exception." (See page 38, column 1, Lines 5-8). Hernandez et al. further teach that both *V. negundo* and *V. rotundifolia* have shown insect repellent activity and other *Vitex*

species are being investigated for pest control activity. (See page 38, column 1, Lines 9-19).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims***  
***(MPEP §2141.012)***

Ross lacks a teaching wherein the repellent composition comprises a portion or extract of the plant Vitex agnus-castus. This deficiency is cured by the teachings of Watanabe et al. and Hernandez et al.

***Finding of Prima Facie Obviousness Rational and Motivation***  
***(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add an insect repellent extract isolated from the leaves of Vitex agnus-castus, as suggested by Watanabe et al. and Hernandez et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Watanabe et al. teach that an insect repellent extract from Vitex rotundifolia is suitable and more advantageous alternative to DEET. Hernandez et al. teach that a variety of Vitex species possess compounds with insect repellent properties. Therefore, it would have been obvious to one of ordinary skill in the art to use extracts of Vitex agnus-castus as an insect repellent to be added to the composition taught by Ross in order to reduce the amount of DEET needed and thereby reduce the negative effects of DEET to the environment and individual.

With regard to, instant claims 46-52, claimed use of the composition as an insect repellent useful against ticks, mites, flies, tabanids, simuliids, creatopogonids, gnats, sand flies, mosquitoes, lice and bugs, is not given patentable weight in product claims as it is an intended use.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call

Art Unit: 1616

800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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